

CLAIMS

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1. A non-invasive method for facilitating the diagnosis of a subject for a tissue remodelling-associated condition, comprising:

obtaining a urine sample from a subject; and
detecting an enzyme in the urine sample, thereby facilitating the diagnosis of the subject for the tissue remodelling-associated condition.

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2. ~~The method of claim 1, wherein the tissue remodelling-associated condition is cancer.~~

3. ~~The method of claim 1, wherein the tissue remodelling-associated condition is an arthritic condition, an obstructive condition, or a degenerative condition.~~

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4. ~~The method of claim 2, wherein the cancer is organ-confined prostate cancer.~~

5. ~~The method of claim 2, wherein the cancer is metastatic prostate cancer.~~

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6. ~~The method of claim 2, wherein the cancer is in cells of epithelial origin.~~

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7. ~~The method of claim 6, wherein the cancer is selected from the group consisting of cancers of the nervous system, breast, retina, lung, skin, kidney, liver, pancreas, genito-urinary tract, and gastrointestinal tract.~~

8. ~~The method of claim 2, wherein the cancer appears in cells of mesodermal origin.~~

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9. ~~The method of claim 2, wherein the cancer appears in cells of endodermal origin.~~

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10. ~~The method of claim 2, wherein the cancer affects cells of bone or of hematopoietic origin.~~

11. ~~The method of claim 1, wherein the enzyme is involved in a pathway of tissue remodelling or reshaping.~~

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- 12. The method of claim 1, wherein the enzyme is a matrix-digesting enzyme.
- 13. The method of claim 1, wherein the enzyme is a protease.
- 14. The method of claim 13, wherein the protease is a serine protease.
- 15. The method of claim 13, wherein the protease is a matrix metalloproteinase.

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- 16. The method of claim 1, wherein the enzyme is a proenzyme.
- 17. The method of claim 1, further comprising removal of low molecular weight contaminants from the urine prior to the detection step.
- 18. The method of claim 17, wherein the urine is dialyzed.

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- 19. A non-invasive method for facilitating the diagnosis of a subject for a disorder of the prostate, comprising:
obtaining a urine sample from a subject ; and
detecting a prostate disorder-associated enzyme in the urine sample, thereby facilitating the diagnosis of the subject for the prostate disorder.

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- 20. The method of claim 19, wherein the prostate-disorder associated enzyme is a matrix-digesting enzyme.

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- 21. The method of claim 19, wherein the matrix-digesting enzyme is a protease.
- 22. The method of claim 21, wherein the enzyme is a metalloproteinase.
- 23. The method of claim 19, wherein the disorder of the prostate is benign prostatic hyperplasia.

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- 24. The method of claim 19, wherein the disorder of the prostate is organ-confined prostate cancer.

- 25. The method of claim 19, wherein the subject has previously been treated surgically or hormonally.

~~26. The method of claim 25, wherein the subject has been treated to block testosterone.~~

5 ~~27. The method of claim 19, wherein the disorder is metastatic cancer.~~

~~28. A method for facilitating the diagnosis of a subject for prostate cancer, comprising:
obtaining a urine sample from a subject suspected of having prostate cancer;
10 and
detecting a prostate cancer-associated enzyme in the urine sample, thereby facilitating the diagnosis of the subject for prostate cancer.~~

15 ~~29. The method of claim 28, wherein the prostate cancer-associated enzyme is a protease.~~

~~30. The method of claim 29, wherein the protease is a matrix metalloproteinase.~~

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~~31. The method of claim 30, wherein the matrix metalloproteinase is gelatinase A or gelatinase B.~~

~~32. The method of claim 28, wherein the subject has benign prostatic hyperplasia.~~

25 ~~33. The method of claim 28, wherein the subject is under treatment to block testosterone.~~

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~~34. The method of claim 28, further comprising removal of low molecular weight contaminants from the urine prior to the detection step.~~

35 ~~35. A method for facilitating the prognosis of prostate cancer in a subject, comprising:
obtaining a biological sample from a subject ; and
detecting a prostate cancer-associated enzyme, thereby facilitating the prognosis of prostate cancer in a subject.~~

~~36. The method of claim 35, wherein the biological sample is urine.~~

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- 37. The method of claim 35, wherein the prostate cancer associated-enzyme is a tissue remodelling-associated enzyme.
- 5 38. The method of claim 37, wherein the prostate-cancer associated enzyme is a protease.
- 39. The method of claim 38, wherein the protease is a type IV collagenase.
- 10 40. The method of claim 39, wherein the metalloproteinase has a molecular weight of approximately equal to or greater than 82 kDa or 92 kDa.
- 41. The method of claim 39, wherein the metalloproteinase has a molecular weight of approximately 72 kDa.
- 15 42. The method of claim 35, wherein the subject has benign prostatic hyperplasia.
- 20 43. A method for prognosis of problematic prostatic hyperplasia in a subject, comprising:
 - obtaining a biological sample from a subject; and
 - detecting a problematic prostatic hyperplasia-associated enzyme in the biological sample, thereby facilitating the prognosis of problematic prostatic hyperplasia in a subject.
- 25 44. The method of claim 43, wherein the prostatic hyperplasia-associated enzyme is a metalloproteinase.
- 45. The method of claim 44, wherein the metalloproteinase has a molecular weight of approximately equal to or greater than 92 kDa.
- 30 46. A method for prognosis of metastatic prostate cancer comprising:
 - obtaining a biological sample from a subject; and
 - detecting a metastatic prostate cancer-associated enzyme in the biological sample, thereby facilitating the prognosis of metastatic prostate cancer in a subject.
- 35 ~~47. The method of claim 1, wherein the enzyme has a molecular weight of approximately 72 kDa or approximately 92 kDa.~~

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48. ~~The method of claim 1, wherein the enzyme has a molecular weight equal to or greater than approximately 150 kDa.~~

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49. ~~The method of claim 43 or 46, further comprising removal of low molecular weight contaminants from the urine prior to the detection step.~~

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50. ~~The method of claim 1, wherein the enzyme is detected electrophoretically.~~

51. The method of claim 50, wherein the electrophoretic pattern is a zymogram.

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52. The method of claim 51, wherein the zymogram substrate is gelatin, casein, fibronectin, vitronectin, plasmin, plasminogen, type IV collagen, or a derivative of type IV collagen.

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53. The method of claim 1, wherein the enzyme is detected immunochemically.

54. The method of claim 53, wherein the enzyme is detected by a radio-immune assay.

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55. The method of claim 53, wherein the enzyme is detected by an enzyme-linked immunosorbant assay.

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56. A kit for facilitating the diagnosis and prognosis of a tissue remodelling-associated condition, comprising:
a container having a reagent for detecting an enzyme in a urine sample; and
instructions for using said reagent for detecting the enzyme for facilitating the diagnosis and prognosis of a tissue remodelling-associated condition.

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57. The kit of claim 56, wherein the tissue remodelling-associated condition is cancer.

58. The kit of claim 56, wherein the tissue remodelling-associated condition is an arthritic condition, an obstructive condition, or a degenerative condition.

- 59. The kit of claim 57, wherein the cancer is organ-confined prostate cancer.
- 60. The kit of claim 57, wherein the cancer is metastatic prostate cancer.
- 5 61. The kit of claim 56, wherein the enzyme is a matrix metalloproteinase.
- 62. The kit of claim 61, wherein the matrix metalloproteinase is a gelatinase.
- 10 63. The kit of claim 56, further comprising an apparatus for separating urine into components for removal of low molecular weight contaminants.

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